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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

DEJONG, ERIC S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,167

Applicant(s)

USUKA ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/21/2006 has been entered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See for example the specification at page 10, lines 2 and 3. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicant's amendment to the specification, filed 02/21/2006, is acknowledged, however, said amendment did not address the embedded hyperlink present on page 10, lines 2 and 3.

Claim Rejections - 35 USC § 112, First Paragraph

The rejection of claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of amendments made to the instant claims as well as arguments presented by applicants.

Claim Rejections - 35 USC § 112, Second Paragraph

The previous rejection of claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of amendments made to the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 17, 20, 22, 39, 42, 45-47, and 58 each recite the limitation of "said one or more genotypic data structures that are not in said one or more genotypic data structures" (see lines 18 and 19 of claim 14, 18 and 19 of claim 17, line 18 and 19 of claim 20, lines 18 and 19 of claim 22, lines 27 and 28 of claim 39, lines 27 and 28 of claim 42, lines 28 and 29 of claim 45, lines 26 and 27 of claim 46, lines 26 and 27 of claim 47, and lines 25 and 26 of claim 58). There is insufficient antecedent basis for this limitation in the instant claims, as the claims do not recite any limitation or step drawn to identifying or determining a set of genotypic data structures that are not in the group of genotypic data structures resulting from the previously recited step of "repeating said establishing and determining steps" in the instant claims (see for example, lines 10-13 of claim 14). Further, the instant claims fail to provide any step wherein the correlation values are determined or established for genotypic data structures that are not in the

group of genotypic data structures resulting from the previously recited step of "repeating said establishing and determining steps". As such, the metes and bounds of the instant claims are rendered indefinite as it unclear what the determined correlation values of genotypic data structures are relative to in order to determine if a high correlation value is present.

Claims 14, 17, 20, 22, 39, 42, 45-47, and 58 each recite the limitation of "the correlation value for each respective genotypic data structure in the one or more genotypic data structures is a high correlation value relative to the correlation values of genotypic data structures that are not in said one or more genotypic data structures" (see lines 15-19 of claim 14, 15-19 of claim 17, line 15-19 of claim 20, lines 15-19 of claim 22, lines 24-28 of claim 39, lines 24-28 of claim 42, lines 24-29 of claim 45, lines 23-27 of claim 46, lines 23-27 of claim 47, and lines 22-26 of claim 58). The use of the relative term "high correlation value" is indefinite as the neither the instant claims nor the instant specification provide a requisite threshold for when a given correlation value is to be considered a "high correlation value". For example, it is unclear if the requisite of a "high correlation value" is satisfied by any given correlation value when said given value simply is greater than any of the correlation values of genotypic data structures that are not in said one or more genotypic data structures. Alternatively, it is unclear if the requisite of a "high correlation value" is satisfied only when a given correlation value has a large numerical value above some set threshold (ex: a given correlation value is considered high only when it is 50% greater than any of the correlation values of

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genotypic data structures that are not in said one or more genotypic data structures). As such, the metes and bounds of the instant claims are rendered indefinite.

Claims 14, 17, 20, 22, 39, 42, 45-47, and 58 each recite the limitation of “an amount of said genome is included in each locus in said plurality of loci is predetermined” (see lines 21 and 22 of claim 14, lines 21 and 22 of claim 17, lines 21 and 22 of claim 20, lines 21 and 22 of claim 22, lines 30 and 31 of claim 39, lines 30 and 31 of claim 42, and lines 31 and 32 of claim 45, lines 20 and 21 of claim 46, lines 29 and 30 of claim 47, and lines 28 and 29 of claim 58). This limitation is unclear as the instant claims do not set forth what “an amount of said genome” that is “predetermined” is predetermined with respect to. Further, the instant specification does not provide any explicit definition that defines what “an amount of said genome” that is “predetermined” is predetermined with respect to.

For the purpose of continuing examination, the limitation of “an amount of said genome is included in each locus in said plurality of loci is predetermined” has been construed to read on any determination of an amount of a given genome included in each locus in a plurality of loci wherein the determination occurs before or at the time of performing the step of identifying one or more genotypic data structures in said plurality of genotypic data structures (see for example lines 14-22 of claim 14).

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Claims 15, 21, and 40 are also included under the above rejections under 35 § USC 112, second paragraph due to their dependence from either of claims 14, 20, and 39, respectively.

Claim Rejections - 35 USC § 101

The previous rejection of claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter. However, the rejection of claims under 35 U.S.C. 101 as being directed to non-statutory subject is found appropriate on the newly presented basis discussed below.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regards to claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58, the instant claims are drawn to methods and related computer system and program products for associating a phenotype with one or more candidate chromosomal region in a genome of a species. Said methods and related computer system and program products are considered non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or an useful, tangible

and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include any tangible result. A tangible result requires that the claims must set forth a practical application of the above described methods and related computer system and program products to produce a real-world result.

The instant claims recites steps drawn to establishing a genotypic data structure, determining a correlation value for said genotypic data structure, determining a correlation value for said data structure, repeating said establishing and determining steps for each locus in a plurality of loci, identifying one or more genotypic data

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structures in a plurality of genotypic data structures, fitting a distribution of a plurality of variations from a probability function, and weighting each variation by a corresponding value derived from said probability function. However, these steps only suggest that the above described determinations and calculations have been performed without further requiring that a result be communicated to a practitioner the instantly claimed invention. Further, the instant claims do not require performing any step involving a physical transformation, such as experimentally a genomic assay on a plurality of loci so as to acquire genotypic data for a genotypic data structure. As such, the instant claims do not explicitly include any tangible result.

Response to Arguments

Applicant's arguments with respect to claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 have been considered but are moot in view of the new grounds of rejection presented above.

Conclusion

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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John S. Brusca 13 May 2000
JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER

EXAMINER INTERVIEW

On February 1, 2006, Attorney for Applicants, Brett Lovejoy, held an Examiner Interview with Examiner DeJong to discuss the objections and Rejections maintained in the January 12, 2006 Advisory Action. Applicants wish to thank Examiner DeJong for the courtesies extended in the Examiner Interview.

Objections to the Specification. Examiner DeJong and attorney for Applicants discussed the objection to URLs present in the specification. Examiner DeJong explained that browser-executable code was not permissible in the patent application specification. Attorney for Applicants duly noted this explanation and, in the instant paper, amendments to the specification have been made to remove any recitation of the phrase "http://" or "www." As such, Applicants believe the specification for the above-identified application no longer contains browser-executable code. Thus, Applicants respectively request that this objection be withdrawn.

Rejection of the claims under 35 U.S.C. § 112, First Paragraph. Examiner DeJong and attorney for Applicants also discussed the rejection of claims 14, 15, 17, 20, 22, 39, 42, 45-47, and 58 under 35 U.S.C. § 112, first paragraph, for reciting the phrase "plurality of genotypic data structures that are not in said one or more genotypic data structures" in the independent claims. Attorney for Applicants explained that there was written support for this phrase in the specification. Examiner DeJong agreed with Attorney for Applicants on this issue. Agreement on this issue is noted in the February 3, 2006 Interview Summary prepared by Examiner DeJong in which it is noted that the proposed amendment in the Response would be sufficient to overcome the written description rejection of record. Applicants maintain these same claim amendments in the current paper on the basis that the February 3, 2006 Interview summary stated that such claim amendments are sufficient to overcome to the 35 U.S.C. § 112, first paragraph, rejection.

No outstanding rejections of record. Thus, between the January 12, 2006 Advisory Action and the February 3, 2006 Interview Summary, the Examiner has stated that each of the rejections of record would be overcome if the Response were entered. Accordingly, herewith, Applicants have filed a Request for Continued Examination and this paper, which includes the same claim amendments and arguments found in the Response. In particular, this paper is identical in form with respect to arguments raised in the July 20, 2006 Office Action and with respect to claim amendments made in the original response to the July 20, 2006 Office Action. Thus, Applicants expect that entry of the current paper (response) will

Interview Summary Okay
EDJ 05/01/2006